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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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N SCH-1686-C1

EXAMINER

HM12/1003

MILLEN WHITE ZELANO & BRANNIGAN PC
ARLINGTON COURTHOUSE PLAZA I
2200 CLARENDON BOULEVARD STE 1400
ARLINGTON VA 22201

QAZI, S

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

10/03/01

14
23
39

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/619,493

Applicant(s)
Norman Mashed

Examiner
Sabiha Qazi

Art Unit
1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 21, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above, claim(s) 1, 2, 9-11, 14, and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-8, 12, 13, 15-17, and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1, 2, 9-11, 14, and 18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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First office Action on Merits

Invention: Instant invention is drawn to the method of treating premenstrual dysphoric disorder (PMDD) by administering gestagen, estrogen and/or the combination thereof.

Status of the application

Claims 1-23 are pending, 3-8, 12, 13, 15-17 and 19-23 are rejected and 1,2,9-11, 14 and 18 are withdrawn from consideration as non electd invention. No claim is allowed.

Applicant's election of group V (claims 3-8, 12, 13, 15-17 and 19-23) and species of ethinylestradiol and drospirenone with traverse in paper no. 4, dated 9/21/01 is hereby acknowledged. The traversal is on the grounds that there is no serious burden to support the restriction. Furthermore, estrogens and gestagens have the same feature and PCT rules apply. The arguments were fully considered but are not found persuasive. Examiner has given the reasons as to distinctness of each invention, that search required for one will not be the same for the other and thus, a reference against one invention may not be applicable against the other invention. They are patentably distinct. Claims are drawn to the method of treating premenstrual dysphoric disorder (PMDD) by administering gestagen, which is broad and includes dozens of compounds which does not fall in the same class or subclass. Furthermore, methods for treating premenstrual dysphoric disorder (PMDD) by administering estrogen compounds and their mixtures are also claimed which would require different searches. It would be a burden on the examiner to search the whole invention as claimed. The search was limited to the combination of the elected species. This was considered a reasonable search according to MPEP 803.02. Burden is likewise demonstrated by divergent classification, database and other searches for the entire genus would represent excessive burden on the examiner. For the reason cited above and in previous office action the examination of the elected invention is proper. Restriction is made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 3-8, 12, 13, 15-17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuman, Friedmund (CA 118:161077, abstract of Pharm. Ztg. (1992), 137(34), 9-15). Neuman teaches the application of estrogen-progestogen drug combination in gynecology, both for contraception and for the treatment of various disorders such as

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premenstrual syndrome etc. The application forms and side effects are also described. (See abstract)

Instant invention is drawn to the method of treating premenstrual dysphoric disorder (PMDD) by administering gestagen, estrogen and/or the combination thereof.

It would have been obvious to one skilled in the art at the time of invention to use gestagen, estrogen or the combination of both for the treatment of premenstrual disorders particularly when prior art teaches the treatment of premenstrual syndrome by the same compounds.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

The determination to employ the optimum proportion of the ingredients as cited in claims would have been within the skills of the one familiar with the art. These numerical limitations of the molar ratios recited in claims of the instant invention do not distinguish the claims over the prior art because they would have been obvious to one skilled in the art in the absence of a showing of criticality, of unobviousness or unexpected results over the prior art.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

2. Claims 3-8, 12, 13, 15-17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guenther et al. (CA 113:218253, abstract of WO 9004397). Guenther teaches the preparations of estrogen-gestodene drug combination for the treatment of premenstrual syndrome etc.

Instant invention is drawn to the method of treating premenstrual dysphoric disorder (PMDD) by administering gestagen, estrogen and/or the combination thereof.

It would have been obvious to one skilled in the art at the time of invention to use gestagen, estrogen or the combination of both for the treatment of premenstrual disorders particularly when prior art teaches the treatment of premenstrual syndrome by the same compounds.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

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The determination to employ the optimum proportion of the ingredients as cited in claims would have been within the skills of the one familiar with the art. These numerical limitations of the molar ratios recited in claims of the instant invention do not distinguish the claims over the prior art because they would have been obvious to one skilled in the art in the absence of a showing of criticality, of unobviousness or unexpected results over the prior art.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Minor Informalities

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Telephone Inquiry Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



**Sabiha N. Qazi Ph.D.
Primary Examiner,
Art Unit 1616**

10/1/01